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EXPRESS MAIL CERTIFICATE

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EL 983 776 341 US

Date of Deposit

March 10, 2006

Type of Documents

Request for Correction of Error in Patent

(2 pages);

Certificate of Correction (Form PTO/SB/44)

(5 pages);

Copy of PTO-1449, as signed by Examiner

(3 pages);

Return Postcard

Certificate

US Patent No.

6,890,935 BZ

1. Marshall

MAR 1 7 2006

Issue Date

May 10, 2005

of Correction

I hereby certify that the documents identified above are being deposited with the United States

Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date
indicated above and are addressed to the Certificate of Correction Branch, Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313.

Diane H. Marshall

MAR 17 2006



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gary Maurice Dull, et al.

Patent No: 6,890,935 B2) Int. Cl: C07D 401/06

Issued: May 10, 2005) U.S. Cl.: 514/305

For: PHARMACEUTICAL COMPOSITIONS

AND METHODS FOR USE

CORRECTION OF ERROR IN PATENT

Under 37 CFR 1.323
Certificate of Correction of Patent Office Mistake

CERTIFICATE OF CORRECTION OFFICE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Assignee of the above-identified patent hereby requests that a Certificate of Correction be issued for this U.S. Patent. We enclose herewith Form PTO SB/44, which provides the changes as they should be listed.

Assignee requests that several Patent Office errors be corrected in the presently requested Certificate. Assignee requests that the face page of the Patent be corrected to include all of the U.S. Patent Documents (1-20); Foreign Patent Documents (21-31); and Other Documents (32-53) as correctly submitted in Applicants' Information Disclosure Statement of July 30, 2001, and acknowledged by the Examiner May 27, 2002. Assignee requests that the specification as reflected in column 4, line 59 and column 8, line 44 and column 10, line 6 be corrected as indicated in form PTO/SB/44. Assignee requests that claim 1, column 42, line 63 and claim 15, column 44, line 35 and claim 18, column 46, line 16 be corrected as indicated in form PTO/SB/44.

EL 983 776 341 US U.S. Pat. No. 6,890,935 Issued: May 10, 2005

Assignee believes that the submission of the enclosed PTO 1449, initialed and signed by the Examiner, supports the Request for Correction. The Commissioner is hereby authorized to charge any fees which are required, or credit any overpayment to Deposit Account no. 09-0528.

Respectfully submitted,

Carl B. Massey, Jr.

Reg. No. 44,224

Attorney for Assignee

Date: Mach 10, 2006

Womble Carlyle Sandridge & Rice, PLLC

P.O. Box 7037

Atlanta, Georgia 30357-0037

Telephone: (336) 721-3681 / Facsimile: (336) 726-8074

Docket: T103 1401.1

PATENT NO: 6,890,935 B2

DATED:

May 10, 2005

INVENTOR(S):

Gary Maurice Dull, et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the front page, under U.S. Patent Documents, the following should be added,

5,212,188	05/1993	Caldwell	514/343
5,217,975	06/1993	Wadsworth	514/299
5,219,849	06/1993	Lotti	514/214
5,276,043	01/1994	Lippiello	514/343
5,346,906	09/1994	Baker	514/305
5,510,355	04/1996	Bencherif	514/305
5,583,140	12/1996	Bencherif	514/299
5,597,919	01/1997	Dull	544/242
5,604,231	02/1997	Smith	514/256
5,616,707	04/1997	Crooks	544/242
5,616,716	04/1997	Dull	546/300
5,663,356	09/1997	Ruecroft	546/300
5,780,734	07/1998	Goulet	514/19
5,811,442	09/1998	Bencherif	514/384
5,824,692	10/1998	Lippiello	514/343
5,849,764	12/1998	Goulet	514/337
5,852,041	12/1998	Cosford	514/351
5,859,004	01/1999	Olesen	514/214
5,861,423	01/1999	Caldwell	514/351
5,952,339	09/1999	Bencherif	514/294

MAILING ADDRESS OF SENDER: Carl B. Massey, Jr., Esq. (Reg. No. 44,224) Womble Carlyle Sandridge & Rice, PLLC P.O. Box 7037 Atlanta, GA 30357-0037 PATENT NO.: 6,890,935
No of additional copies

Page 1

PATENT NO: 6,890,935 \(\beta \)2

DATED:

May 10, 2005

INVENTOR(S):

Gary Maurice Dull, et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the front page, under Foreign Patent Documents, the following should be added,

WO WO 94/08992 04/1994 WO WO 94/14805 07/1994 WO 95/03306 02/1995 WO WO WO 96/12711 05/1996 WO WO 97/01556 01/1997 WO 97/11072 03/1997 WO WO WO 98/25619 06/1998 WO 98/54181 12/1998 WO WO 99/00385 01/1999 WO WO WO 99/32117 07/1999 WO 00/34276 06/2000 WO

MAILING ADDRESS OF SENDER: Carl B. Massey, Jr., Esq. (Reg. No. 44,224) Womble Carlyle Sandridge & Rice, PLLC P.O. Box 7037 Atlanta, GA 30357-0037 PATENT NO.: 6,890,935
No of additional copies

Page 2

PATENT NO: 6,890,935 62

DATED:

May 10, 2005

INVENTOR(S):

Gary Maurice Dull, et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the front page, under Other Publications, the following should be added,

Barnes, P.J., "Molecules in Focus Nuclear Factor-KB," Int. J. Biochem. Cell. Biol., 29(6): 867-870 (1997).

Birtwistle, J., "The Role of Cigarettes and Nicotine in the Onset and Treatment of Ulcerative Colitis," *Postgrad. Med., J., 72*: 714-718 (1996).

Ebadi, et al., "Neurotophins and Their Receptors in Nerve Injury and Repair," Neurochem., Int., 30(4/5): 347-374 (1997).

Hanisch, et al., "Modulation of Hippocampal Acetylocholine Release: A Potent Central Action of Interleukin-3," The Journal of Neuroscience, 13(8): 3368-3374 (1993).

Holladay, et al., "Neuronal Nicotinic Acetylcholine Receptors as Targets for Drug Discovery," J. Med. Chem., 40(26): 4169-4194 (1997).

Miller, J.G., "Neural-Immune Interactions in Sympathetic Ganglia," TINS, 16(10): 419-423 (1993).

Madretsma, et al., "In-Vivo Effect of Nicotine on Cytokine Production by Human Non-Adherent Mononuclear Cells," European J. of Gastroen. & Hepat., 8(10): 1017-1020 (1996).

Madretsma, et al., "Nicotine Inhibits the In Vitro Production of Interleukin 2 and Tumour Necrosis Factor α by Human Mononuclear Cells," *Immunopharmacology*, 35: 47-51 (1996).

Matthys, P. and A. Billiau, "Cytokines and Cachexia," Nutrition, 13: 763-770 (1997).

Olesen, et al., "Identification of Novel (Isoxazole) Methylene-1-Azabicyclic Compounds with High Affinity for the Central Nicotinic Cholinergic Receptor," *Bioorganic & Medicinal Chemistry Letters*, 7(15): 1963-1968 (1997).

Olivio, et al., "Syntheses of New Open-Ring and homo-Epibatidine Analogues from Tropinone," J. Org. Chem., 64(13): 4966-4968 (1999).

MAILING ADDRESS OF SENDER:
Carl B. Massey, Jr., Esq. (Reg. No. 44,224)
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P.O. Box 7037
Atlanta, GA 30357-0037

PATENT NO.: 6,890,935
No of additional copies

Page 3

PATENT NO: 6,890,935 62

DATED:

May 10, 2005

INVENTOR(S):

Gary Maurice Dull, et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the front page, under Other Publications, the following should be added,

Peacock, et al., "The Effect of Nicotine on Reproduction and Attachment of Human Gingival Fibroblasts in Vitro," J. Periodontal, 64(7): 658-665 (1993).

Pullan, R.D., "Colonic Mucus, Smoking and Ulcerative Colitis," Ann R. Coll. Surg. Engl., 78: 85-91 (1996).

Pullan, et al., "Transdermal Nicotine for Active Ulcerative Colitis," The New England Journal of Medicine, 330(12): 811-815 (1994).

Sandborn, et al., "Nicotine Tartrate Liquid Enemas for Mildly to Moderately Active Left-Sided Ulcerative Colitis Unresponsive to First-Line Therapy: A Pilot Study," Ailment Pharmacol. Ther., 11: 663-671 (1997).

Balfour, S.R., "Pathogenesis and Immune Mechanisms of Chronic Inflammatory Bowel Diseases," *The American Journal of Gastroenterology*, "92(12): 5S-11S (1997).

Secor, H. and J. Seeman, "The Preparation of 'Elongated' Nicotine Analogues," *Heterocycles*, 24(6): 1687-1698 (1986).

Silverstein, et al., "Cigarette Smoking and Ulcerative Colitis: A Case-Control Study," Mayo Clin. Proc., 69: 425-429 (1994).

Van Dijk, et al., "Nicotine Inhibits Cytokine Synthesis by Mouse Colonic Mucosa," European Journal of Pharmacology, 278: R11-R12 (1995).

Wallace, J. and B. Chin, "Inflammatory Mediators in Gastrointestinal Defense and Injury," *Proc. Soc. Exp. Biol. Med.*, 214: 192-203 (1997).

Yanina, et al., Khim-Karm, 21(7): 808-811 (1987).

Zijlstra, et al., "Effect of Nicotine on Rectal Mucus and Mucosal Eicosanoids," Gut, 35: 247-251 (1994).

MAILING ADDRESS OF SENDER: Carl B. Massey, Jr., Esq. (Reg. No. 44,224) Womble Carlyle Sandridge & Rice, PLLC P.O. Box 7037 Atlanta, GA 30357-0037 PATENT NO.: 6,890,935
No of additional copies

Page 4

PATENT NO: 6,890,935 B2

DATED:

May 10, 2005

INVENTOR(S):

Gary Maurice Dull, et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification:

Column 4, line 59, add comma after "-O(CR'R") rNR'R"

Column 8, line 44, "yrrolidine" should read, "pyrrolidine"

Column 10, line 6, "Snylett" should read "Synlett"

In the Claims:

Claim 1, column 42, line 63, "heterocycly" should read, "heterocyclyl"

Claim 15, column 44, line 35, "and X" should be added after "nitrogen"

Claim 18, column 46, line 16, "heterocycly" should read, "heterocyclyl"

MAILING ADDRESS OF SENDER: Carl B. Massey, Jr., Esq. (Reg. No. 44,224) Womble Carlyle Sandridge & Rice, PLLC P.O. Box 7037 Atlanta, GA 30357-0037 PATENT NO.: 6,890,935
No of additional copies

Page 5

								Sheet 1 of 3
FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office				Attorney Docket Number 627-325IP		CENO9/845,56		
LIST OF DOCUMENTS CITED BY APPLICANT							YE	
Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Applicants: Dull et al.			EIVED 3 1 2001 ER 1600/2900	
(S) 3 4 1 9	S 3410				Filing Date: April 30, 2001			Group 16 9 4
			U. S. P.	ATENT DOCU	MENTS			١
Examiner Initial		Document Number	Date	N	ame	Class	Subclass	Filing Date if Appropriate
VΒ	1.	5,212,188	05/18/93	Caldwell et a	i.	514	343	
VB	2.	5,217,975	06/08/93	Wadsworth e	t al.	514	299	
V13	3.	5,219,849	06/15/93	Lotti et al.		514	214	
VB	4.	5,276,043	01/04/94	Lippiello et a	l.	514	343	Ì
VB	5.	5,346,906	09/13/94	Baker et al.		514	305	
\VB	6.	5,510,355	04/23/96	Bencherif et a	al.	514	305	
is	7.	5,583,140	12/10/96	Bencherif et al.		514	299	
Vis	8.	5,597,919	01/28/97	Dull et al.		544	242	
m	9.	5,604,231	02/18/97	Smith et al.		514	256	
N KK	10.	5,616,707	04/01/97	Crooks et al.		544	242	
N)	11.	5,616,716	04/01/97	Dull et al.		546	300	
m	12.	5,663,356	09/02/97	Ruecroft et al	l .	546	300	
(n)	13.	5,780,734	07/14/98	Goulet et al.		514	19	
Ŵ	14.	5,811,442	09/22/98	Bencherif et a	al.	514	384	
1/3	15.	5,824,692	10/20/98	Lippiello et a	l .	514	343	
The state of the s	16.	5,849,764	12/15/98	Goulet et al.		514	337	
\$\\ \\\ \\\	17.	5,852,041	12/22/98	Cosford et al.		514.	351	
VÝ	18.	5,859,004	01/12/99	Olesen		514	214	
vŋ	19.	5,861,423	01/19/99	Caldwell et al.		514	351	
m	20.	5,952,339	09/14/99	Bencherif et al.		514	294	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Со	untry	Class	Subclass	Translation Yes No
VD	21.	WO 94/08992	04/28/94	PCT		G 07D	401/1 2	<u></u>
h	22.	WO 94/14805	07/07/94	PCT		C07D	453/02	
<i>V</i> ₂	23.	WO 95/03306	02/02/95	PCT		C 07D	487/08-	

EXAMINER EXAMINER

V. Balosnhamern

DATE CONSIDERED 5/27/62_

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office			Attorney Docket Number 627-325IP		CESeria N CESeria N CESP/845,5 EH				
LIST	LIST OF DOCUMENTS CITED BY APPLICANT			NT					<
DESTRIBER S	(Use several sheets if necessary)							2001 1600/2900	m
77	LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Applicants: Dull et al.			ă U	
					Filing Date: April 30, 20	01		Group 1694	
1/4	24.	WO 96/12711	05/02/96	PCT		C07D	271/08		
VA	25.	WO 97/01556	01/16/97	PCT		C 07D	413/06		
V	26.	WO 97/11072	03/27/97	PCT		C 07 D	453/02		
13	27.	WO 98/25619	06/18/98	PCT		A61K	31/505		
Vy	28.	WO 98/54181	12/03/98	PCT		C 07D	451/02		
V)	29.	WO 99/00385	01/07/99	РСТ		C67D	453/02		
V)	30.	WO 99/32117	07/01/99	PCT		A61K	31/44		
V)	31.	WO 00/34276	06/15/00	PCT		C 07D	453/0 2		
′								<u> </u>	
		OTHER DOCUM	MENTS (Inclu	iding Author, T	itle, Date, Pertin	ent Pages, E	ic.)	·	
Vy	32.	Barnes, Peter J., "MOLECULES IN FOCUS Nuclear Factor-KB," Int. J. Biochem. Cell Biol., 29:6 867-870 (1997).							
W	33.	Birtwistle, Jon, "The Role of Cigarettes and Nicotine in the Onset and Treatment of Ulcerative Colitis," Postgrad Med. J., 72: 714-718 (1996).							
り	34.	Ebadi et al., "Neurotophins and Their Receptors in Nerve Injury and Repair," Neurochem Int., 30:4/5 347-374 (1997).							
V	35.	Hanisch et al., "Modulation of Hippocampal Acetylcholine Release: A Potent Central Action of Interleukin-2," <i>The Journal of Neuroscience</i> , 13:8 3368-3374 (1993).							
W	36.	Holladay et al., "Neuronal Nicotinic Acetylcholine Receptors as Targets for Drug Discovery," J. Med. Chem., 40:26 4169-4194 (1997).							
W	37.	Jonakait, G. Miller, "Neural-Immune Interactions in Sympathetic Ganglia," TINS, 16:10 419-423 (1993).							
M	38.	Madretsma et al., "In-Vivo Effect of Nicotine on Cytokine Production by Human Non-Adherent Monomuclear Cells," European J. of Gastroen & Hepat, 8:10, 1017-1020 (1996).							
V	39/	Madretsma et al., "Nicotine Inhibits the in Vitro Production of Interleukin 2 and Tumour Necrosis Factor- α by Human Mononuclear Cells," <i>Immunopharmacology</i> , 35 47-51 (1996).							
M	40.	Matthys, P. & Billiau, A., "Cytokines and Cachexia," Nutrition, 13 763-770 (1997).							
Ŋ	41.	Olesen et al., "Identification of Novel (Isoxazole)Methylene-1-Azabicyclic Compounds with High Affinity for the Central Nicotinic Cholinergic Receptor," <i>Bioorganic & Medicinal Chemistry Letters</i> , 7:15 1963-1968 (1997).							
W	42.	Olivo et al., "Syntheses of New Open-Ring and homo-Epibatidine Analogues from Tropinone," J. Org. Chem., 64:13 4966-4968 (1999).							
M	43.	Peacock et al., "The Effect of Nicotine on Reproduction and Attachment of Human Gingival Fibroblasts in Vitro," <i>J. Periodontal</i> , 64:7 658-665 (1993).							

EXAMINER EXAMINER

		4 ()					
FORM PTO-		S. Department of Commerce nd Trademark Office	Attorney Docket Number 627-3251P	ECH CENTER 1500/2900			
LIST OF DOCUMENTS CITED BY APPLICANT				3 1 2001 NTER 1500/			
(Use several sheets if necessary)			Applicants: Dull et al.	VED 2001 2001 200129			
JUL 3 0 2001			Filing Date: April 30, 2001	Group 16 9 4			
SP	44.	Pullan, Rupert D., "Colonic Mucus, Smoking (1996).	and Ulcerative Colitis," Ann R. C	Coll. Surg Engl., 78 85-91			
Ŋ	45.	Pullan et al., "Transdermal Nicotine for Active Ulcerative Colitis," The New England Journal of Medicine, 330:12 811-815 (1994).					
V	46.	Sandborn et al., "Nicotine Tartrate Liquid enemas for Mildly to Moderately Active Left-Sided Ulcerative Colitis Unresponsive to First-Line Therapy: A Pilot Study," <i>Ailment Pharmacol. Ther.</i> , 11 663-671 (1997).					
٧̈́	47	Sartor, R. Balfour, M.D., "Pathogenesis and Immune Mechanisms of Chronic Inflammatory Bowel Diseases," <i>The American Journal of Gastroenterology</i> , 92:12 5S-11S (1997).					
ν	48.	Secor, H. & Seeman, J., "The Preparation of 'Elongated' Nicotine Analogues," <i>Heterocycles</i> , 24:6 1687-1698 (1986).					
M	49.	Silverstein et al., "Cigarette Smoking and Ulcerative Colitis: A Case-Control Study," Mayo Clin. Proc., 69 425-429 (1994).					
<i>\\</i> >	50.	Van Dijk et al., "Nicotine Inhibits Cytokine Synthesis by Mouse Colonic Mucosa," European Journal of Pharmacology, 278 R11-R12 (1995).					
V	51.	Wallace, J. & Chin, B., "Inflammatory Mediators in Gastrointestinal Defense and Injury," <i>Proc. Soc. Exp. Biol. Med.</i> , 214 192-203 (1997).					
VS	52.	Yanina et al., KhimKarm, 21:7 808-811 (1987).					
1/5	53.	Zijlstra et al., "Effect of Nicotine on Rectal Mucus and Mucosal Eicosanoids," Gut, 35 247-251 (1994).					

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